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| EXAMINER | |
|---|---|
| GAKH, YELENA G | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1743 | |

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/092,837 | BACH ET AL. | |
| | Examiner | Art Unit | |
| | Yelena G. Gakh, Ph.D. | 1743 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *27-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Amendment filed 07/29/05 is acknowledged. Claims 27-38 are pending in the application.

### *Response to Amendment*

2. The grounds for rejections are reconsidered for correct pending claims.

### *Specification*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The specification is objected to as not being written in "such full, clear, concise, and exact terms" as to enable any person skilled in the art to practice the invention in its best mode.

Specifically, the "Summary" does not provide a clear idea of the essence of the invention. From the Summary it is completely unclear, how "determination of an item of interest in a sample" is performed. It is not clear, what the whole expression "a sample is provided accessible to the single structure" might mean. What is a "single structure"? Can a single conveyer with several different stations be considered "a single structure"? Also, what kind of a sample would be *inaccessible* to the structure? It is not apparent, if there is any connection between adding a reagent to this container and separation of "the item of interest". If there is no connection, then it is not clear, why the reagent is added, and how "the item of interest" is separated, or why it could not be separated before adding the reagent. The following expression is so confusing that the examiner fails to understand its meaning: "content of the second container is brought to a first temperature different form a temperature of the first process path in the second process path". What is "a temperature of the first process path in the second process path"? How the item of

interest in the second container is detected? Why the temperature should be different for the item to be detected? The Summary of the invention is written in a very confusing and unclear language.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 27-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites "a method of performing a determination of an item of interest in a sample" in its preamble, and "detecting the item of interest" as the last step in the body. "Determination" and "detection" are not synonyms, as correctly noted by the Applicants. While "detection" answers a question, if the item is present or not, "determination" means defining what exactly is present. The preamble and the body of the claim are not in accordance with each other. From step b) it is not clear, if the separation occurs within the container, and if it does, it is not clear as to how the separated item of interest and the content of the container are kept separated, while being together in the container. Moreover, from claim 27 it is not clear, why the item of interest should be detected at all, if it is known that it is present in the sample?

Claim 29 is not clear as to why at least one of two containers should be sealed just for the seal to be removed in the next step?

Claim 30 is not clear, as to which contaminant is meant here - the one inside the containers, or outside the containers.

In claim 31 it is not clear as to how the second process path is related to the temperature of the container? If it is the temperature of the second container that is changed from the first to the second value, and the container is in the second path, then what the second path refers to in this claim?

Claim 32 recites "the second first container", the expression, which does not make any sense. Since only one container is recited in the parent claim, there cannot be "the second first container". If a plurality of containers is meant to be recited in the claims, this should be indicated in the parent claim; the expression "second first container" is very confusing and should be changed. Further, claim 32 is not clear as to what is meant by "a reagent" in the claim, if it does no react with the "item of interest". What does it react with? The essence of the claim is not apparent.

In claim 33 it is not clear as to how the sample can be maintained at more than one temperature? According to the Dictionary.com *maintain* is "to keep in an existing state; preserve or retain". The sample cannot be maintained in "an existing state", if the state is changing.

The essence of claim 35 is completely unapparent. It sounds like the sample is transferred to the container just to be separated from the content of the container (then why should it be transferred to the container with such an unfavorable content?); brought to a first temperature (was it at no temperature before?); with following moving the container (which presumably should not contain any item of interest, since the item of interest is separated from the content of the container, and therefore *is not* a content of the container); bringing the item of interest to the second (third (?) temperature); and detecting the item of interest in the container, although it supposedly should not be there. What does it all mean? The claim is completely unclear.

Which contaminant is meant in Claim 36? The one present in the container? Then why should the sample with the item of interest be brought into the container, which has the contaminant?

What the expression, "discerning determinations to be performed by the single structure" is meant in claim 37? What does the single structure perform? What type of sorting is meant in the claim?

In conclusion, the claims are written in such unclear and indefinite terms, that it is difficult to understand the essence of the invention and the purpose of the method recited in the claims. While the specification should support the claims and describe the invention in greater details, the claim language should be clear and definite on its own. From the claims of the instant application it is not clear at all as to what the recited method aims to.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 27-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoskins et al. (US 3,883,305, IDS).

Hoskins teaches a method of automatic chemical analysis, comprising transferring a sample to a first container in a first process path 5, incubating it at the first temperature, transferring the sample from the first container to the second container in the second path 26 and bringing content of the second container to a second temperature different from the first one using a heater 30, and detecting the item of interest in the second path with a detector 43. While Hoskins does not teach a plurality of "sub-paths", it would have been obvious for any person of ordinary skill in the art to add sub-paths to the Hoskins's apparatus in order to expand the potentials of the method.

11. **Claims 27-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Choperena et al. (US 5,380,487) in view of Hoskins.

Choperena discloses a device and method for automatic chemical analysis, the method comprising placing a plurality of containers in a first process path (54) on a single structure, transferring samples comprising analytes and reagents (32) into the containers, mixing them, separating analytes, transferring separated analytes in the containers in the second process path (60) and detecting the analyte ("the item of interest") (col. 9 and 10). The washing station can be on the same path as a detector, or on the first process path (col. 17, lines 3-15, Figure 7). Controlled different temperatures are used for keeping reagents at a refrigerator temperature, incubating reaction mixtures at higher temperatures and detecting the analytes (col. 9, lines 45-70). A detailed description of scheduling of the events according to the processes is presented in the Summary of the Invention.

While Choperena does not specifically disclose sealing the vessels between the measurements, it is a conventional and obvious feature of any analysis, which makes it obvious for any routineer in the art to imply.

Choperena discloses transferring containers (vessels) from one path to another, rather than transferring samples. Transferring samples from one container into another within different stations is a conventional feature of an automated analysis utilizing automated analyzers, as taught by e.g. Hoskins.

It would have been obvious for any routineer in the art to slightly modify Choperena's method by implying transferring samples from one set of containers to a different set of containers in different paths, as taught by Hoskins, because it is a conventional feature of analysis using a variety of automated analyzers, and because it increases the efficiency of the analysis, since using aliquots of the same sample allows conducting several tests or measurements on the same sample.

***Response to Arguments***

12. Applicant's arguments filed 07/29/05 have been fully considered but they are not fully persuasive. While the examiner admits that the preliminary amendment was missed and

therefore the grounds for rejections for the correct pending claims are reconsidered, several issues raised in the previous Office action are pertinent to the Applicants' arguments.

Objection to the specification (Summary of the Invention):

Rule 37 CFR § 1.73 related to the definition of "summary of the invention" states: "A brief summary of the invention *indicating its nature and substance*, which may include a statement of the object of the invention, should precede the detailed description. Such summary should, when set forth, be commensurate with the invention as claimed and any object recited should be that of the invention as claimed". The examiner did not find any statement in MPEP indicating that it is necessary to read "Background of the Invention" in order to understand the summary of the invention. To the examiner's understanding, the summary of the invention should reflect "in full, clear, concise, and exact terms" the essence of the invention. While the examiner acknowledges the Applicants' amendment to the Summary, which at least somehow directs the invention to the analysis of biological samples, the rest of the Summary is completely blur. If such phrasing as "the method and apparatus according to the present invention pertain to thermal cycling of biological samples such as nucleic acid mixtures using metered amounts of heated or chilled fluids at two or more fixed temperatures" were used in the Summary, the examiner would not have any questions regarding the language of the specification. However, if explanation of the summary of the invention requires a full page of the Applicants' remarks, such summary of the invention cannot be considered acceptable.

The language of the pending claims is so unclear and indefinite, that it is difficult to grasp the essence of the invention from the claims.

Regarding the prior art: to the extent of the examiner's understanding of the inventive method recited in the claims, Hoskins and Choperena teach the method of the instant application with a very small and obviously curable deficiency, which is addressed by the examiner in the present Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh
9/16/05

YELENA GAKH
PRIMARY EXAMINER